

REMARKS

Claims 9-32 remain pending. Favorable reconsideration is respectfully requested.

The present invention relates to a method for alleviating a symptom from lipopolysaccharide-induced inflammation comprising protectively administering to a person orally or parenterally an effective amount of human-type lactoferrin for a time and under conditions effective to alleviate said symptom. See Claims 9, 15, 21 and 27.

As shown in the Examples of the present application, the Inventors have administered human-type lactoferrin protectively before the administration of lipopolysaccharide (LPS), i.e., the lactoferrin was administered protectively as now claimed, to effectively alleviate symptoms of lipopolysaccharide-induced inflammation.

In particular, in Example 4 human-type lactoferrin was administered (1) 18 hours before, (2) 15 minutes before and (3) 60 minutes after the administration of LPS. A much better result was observed in (1) and (2) as compared to (3).

The rejections of the claims under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) over Nitsche are respectfully traversed. Nitsche fails to disclose or suggest the claimed methods.

In the *in vivo* tests described in Examples 3 and 4 of Nitsche, bacteria were inoculated before administration of lactoferrin. Nitsche fails to disclose or suggest that protective administration of lactoferrin, i.e., prior to bacterial invasion, shows a much better effect as compared to administering lactoferrin after invasion of the bacteria. Accordingly, the claimed method is not disclosed or suggested by that reference.

Further, the Examiner states on page 5 of the Office Action mailed March 13, 2006:

However, on col. 12, lines 61-65, the '909 patent clearly states that when lactoferrin was administered intravenously the initial increase in plasma endotoxin activity — one hour after administration of the antibiotic --- was reduced by approx. 58.5% in comparison of the albumin control group. Thus, clearly

showing the reduction of albumin concentration in blood, and as such meets the limitation of claim 21.

Applicants respectfully submit that the Examiner's understanding is inaccurate. The test result does not show the reduction of albumin concentration in blood at all. The description of lines 61 to 65 at column 12 reports only that the group to which Lf (Lcf-Fe(A)) was administered showed approximately 58.5% reduction of endotoxin activity as compared to the endotoxin activity in the group to which albumin was administered in place of said Lf. Specifically, albumin was administered intravenously as a control protein in place of hLf in Nitsche, while it was confirmed by the present inventors that the tested animal's albumin accumulated in the abdominal cavity to which LPS was administered. The description at column 12, lines 61-65 of Nitsche has no relationship with the present invention in which albumin accumulation may be alleviated.

In view of the foregoing, withdrawal of this ground of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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